



ACCOUNTING OF RESEARCH DISCLOSURES

Prep To Research, Waiver Of Authorization, Decedent Data



An Accounting of Disclosures applies when you are issued Preparatory to Research, Waiver of HIPAA authorization or Decedent data collection approval by the IRB/Privacy Officer or Designate.

What is considered a disclosure and what does it mean to account for a disclosure?

A disclosure is the release, transfer, access to, or divulging of information, PHI, protected health information, in any manner outside the entity holding the information.

An accounting of these disclosures is required when PHI, as described above, is disclosed for reasons other than treatment, payment or health care operations or made without an authorization. Collecting PHI at Lifespan for certain reasons, Prep to research, waiver of authorization and collecting decedent data, all without patient/subject authorization, falls into the category of requiring an accounting if a disclosure has occurred.

Who needs to account for these disclosures? No accounting is required if PHI is accessed by, transferred to, released to, etc a member of Lifespan's workforce. (It is important to note here that for research purposes under HIPAA **Foundation employed physician**, and **OHCA (Organized Health Care Arrangement) members ARE NOT** members of Lifespan's workforce). *see <http://intra.lifespan.org/compliance/privacy/policies/CCPM-68.pdf> for Lifespan's OCHA policy.*

According to HIPAA workforce is defined as: Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of the covered entity, whether or not they are paid by the covered entity.

Table below indicated when an accounting is required:

PHI reviewed, accessed, transferred or divulged and subject has not provided authorization	No Accounting Required	Accounting Required
Lifespan Workforce Member	X	
Foundation Employed Physician		X
OHCA Member		X
Lifespan Affiliate Hospital employed physician	X	
Volunteer	X	
CRO		X
DATA has been De-Identified prior to transferring/divulging to someone outside workforce	X	

Any questions regarding Accounting of Disclosures and Research should be addressed to:
Janice Muratori, RNP, MSN, CIP, Director, Research Protection Office and Lifespan HIPAA Research Privacy Officer
jmuratori@lifespan.org, Ph 401 444-6897 Fax 401 444-7960



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How do you account? There are two ways to account for disclosures. The Primary and preferred way is to use Lifespan's Medical Records department Disclosure Tracking System. To learn to use this system someone within your research department, **who is a Lifespan workforce member**, should contact the manager of your affiliated MR department for training in this tracking system. This tracking system has the ability to capture the information required by HIPAA for an accounting of disclosures. See *"Disclosure Tracking System Entry Instructions"* on the ORA website.

There are, unfortunately, limitations to this Disclosure tracking system. The limitations are:

1. Only Lifespan users/employees can gain access to the Disclosure tracking system. IS will not grant access to non-Lifespan members. If you were granted access and you were not a Lifespan workforce member you would view more PHI and more disclosures would occur.
2. Only the names of patients who have been seen at Lifespan since April 2003 are in the system. Therefore, if your review includes charts or records of patients who have not been admitted or seen at Lifespan since April 2003 you will not be able to account for a disclosure using this system. (An alternative method is described below).

Therefore, if you believe you and/or your research includes one of the above limitation issues with the Disclosure tracking system you must maintain a list of all disclosures, charts you have accessed, viewed, received, etc., using a spreadsheet to capture the required data. See sample table below.

What needs to be accounted for:

Date of Disclosure; Name/address of person or entity reviewing, accessing or receiving PHI; a brief description of the PHI reviewed, accessed or received; and a brief statement of the reason for the disclosure.

Sample Disclosure Tracking Data Collection Sheet

Patient Name	DOB	Med. Record #	Information Disclosed	Date of Disclosure	Purpose of Disclosure	Name/address or person receiving reviewing or accessing PHI
Jane Doe	9/9/99	532111	Age, DOB, Primary Diagnosis, Date of Discharge, etc.	Date you reviewed, accessed or received PHI	Research Protocol Number	Name of PI and committee number of study. Address of PI

When a patient comes to Lifespan and requests an accounting of disclosures the Office of Research Administration will contact those PI's that were issued Preparatory to Research, Waiver of HIPAA Authorization or Decedent data collection approval by the IRB/Privacy Officer or Designate. We will then ask you to check your disclosure lists to see if you reviewed, accessed or received PHI of the person requesting an accounting.

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Recommendations for Researcher to eliminate the need for accounting of disclosures:

- Get signed HIPAA authorization whenever possible.
- De-identify the records whenever possible before showing them to someone outside the covered entity (Lifespan) workforce.
- Have someone within the covered entity (Lifespan) workforce review the medical records. This person can search the records for the criteria specified and whittle down the # of records that may need to be viewed by someone outside the workforce. This will decrease the volume of records that would require an accounting
 - Prep to research approval specifies that no information can leave Lifespan. However, if someone outside the workforce, the PI, (if not a Lifespan Workforce member), industry, CRO, etc., comes to Lifespan to help review the records then this would constitute as a disclosure and there would need to be an accounting.
- For information that will go outside Lifespan under a waiver of authorization you have two options to eliminate the need for an accounting.
- De-identify the data before it goes outside Lifespan
- Enter into a limited data set agreement. There is a caveat to this:
 - If you use a limited data set and data set agreement you don't have to account for disclosures for information you send out under a data set agreement. However, the initial disclosure may still be the PI that is not a member of the Lifespan workforce. Keep in mind when you begin your review of records, if someone outside the workforce views the PHI before sending the information out under the data set agreement there is still a disclosure to that outside person and an accounting will be required.

Definitions:

- **Accounting of Disclosures** – a record that describes a covered entity's disclosure of PHI other than for treatment, payment, and health care operations. The accounting must include disclosures that have occurred during the 6 years (or a shorter time period at the request of the individual) prior to the date of the request for an accounting. Disclosures made before the compliance HIPAA date do not require accounting.
- **Authorization** – An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.
- **Data Use Agreement** – An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.
- **Disclosures** – The release, transfer, access to, or divulging of information in any other manner **outside the entity** holding the information.
- **De-Identifying Data** – There are 18 identifiers listed by HIPAA that are included in PHI. To completely de-identify PHI all these identifiers must be removed, deleted, and/or blacked out.
- **PHI** is any individually identifiable health information collected from/on a patient, created or received by Lifespan that relates to: The past, present, or future physical or mental health condition of a patient that could potentially identify that individual, (any of the 18 identifiers coupled with health information = PHI of the individual, relatives, employer or household members. **The 18 identifiers are:**

Name,	Fax number	Health care beneficiary #	address (except State)
email address	member or account #	Dates, such as DOB (except year)	SSN #
certificate/license #	Phone number	Medical record #	biometric id-voice/finger prints
device id #	web URLS	IP address	
vehicle ID #	full face photo	any other unique ID	

- **Individually Identifiable Health Information** – Information that is a subset of health information, including demographic information collected from an individual and is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past present or future physical or mental health or condition of an individual.
- **Limited Data Set** – Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's authorization or a waiver of an alteration of authorization for its disclosure, with a data use agreement.
- **PHI** – Protected Health Information – Individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records and employment records
- **Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.
- **TPO** –Treatment, Payment or Health Care Operations.

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